EXHIBIT 9

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-op-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

EXPERT REPORT OF SEAN NICHOLSON, PH.D.

May 10, 2019

1. QUALIFICATIONS

1. I am a Professor in the Department of Policy Analysis and Management and the Director of the Sloan Program in Health Administration at Cornell University. I am also a Research Associate at the National Bureau of Economic Research. Prior to joining Cornell, I served as an Assistant Professor in Health Care Systems at the Wharton School of the University of Pennsylvania. I have a Ph.D. in economics from the University of Wisconsin-Madison and an A.B. in economics from Dartmouth College. My research and teaching specialty is the economics of health care. My curriculum vitae, including a list of publications, is attached as Appendix A.

2. In my academic career, I have researched the economics of the health care industry, with an emphasis on the biotechnology and pharmaceutical sectors. In this field of study, I have published articles in leading academic journals and presented my research at academic conferences. In addition, I have served as a principal investigator on research projects sponsored by the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, and by leading pharmaceutical companies.

3. My research projects have included identifying what types of firms are most effective at developing drugs, assessing risk in the health care industry, and determining the value of new medical technologies. I have done extensive research on the risks and uncertainties facing pharmaceutical companies. I have also conducted research and offered expert testimony in multiple cases in the pharmaceutical industry. Appendix B contains a list of cases in which I have provided deposition or trial testimony in the last four years.

4. I am being compensated at my standard billing rate of $850 per hour. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. I receive compensation from Cornerstone Research based on its collected staff billings for its support of me in this matter. Neither my compensation in this matter nor my compensation from Cornerstone Research is in any way contingent or based on the content of my opinion or the outcome of this or any other matter.

4. SUMMARY OF OPINIONS

11. Opioid prescriptions have been subject to federal and state laws, treatment guidelines, and regulations. In particular:

a. Prescriptions of Actiq, Fentora and other generic opioid medicines manufactured by the Marketing Defendants are subject to stringent FDA regulations.

b. The Drug Enforcement Agency ("DEA") restricts distribution of the Marketing Defendants' opioid medicines.

c. The Marketing Defendants' opioid medicines are subject to prescription drug monitoring programs ("PDMPs").

d. Other Ohio State programs monitor the Marketing Defendants' opioid product prescribing.

12. The risks associated with prescription opioids were generally well known, and if regulators, the State of Ohio and payors had acted earlier, the alleged harm to the Bellwether Counties could have been limited.

13. Based on my analysis, I find Plaintiffs' claim that the Marketing Defendants' alleged conduct "has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin" to be inconsistent with Teva Defendants' market share for branded opioids in the Bellwether Counties, as well as the marketing expenditure of the Teva USA and Generic Defendants on generic products—both of which were miniscule.

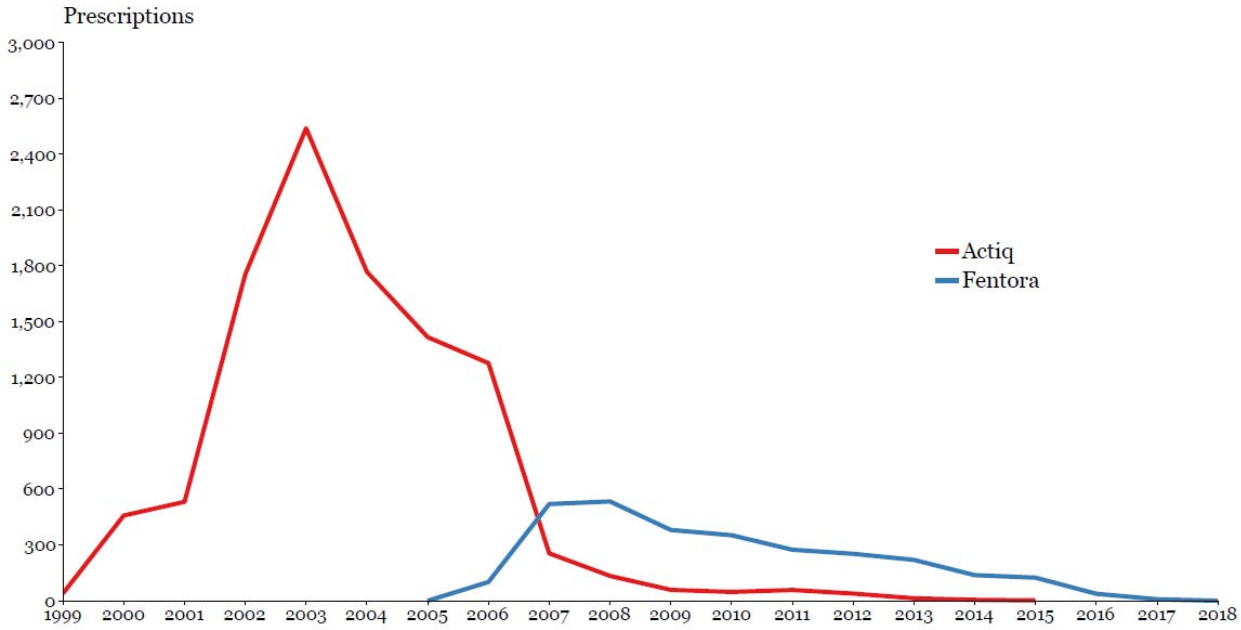
14. Dr. Cutler seeks to estimate "the share of various harms imposed on selected departments in each Bellwether government ('Bellwether divisions') that is attributable to defendants' misconduct." Specifically, Dr. Cutler considers three "categories" of harm:

a. Crime/Public Safety: Sheriff; Juvenile and County courts; Prosecutor and Public Defenders' Office; and Corrections;

b. Children/Family Related: Children and Family Services; and Children Services Board; and

c. Public Health: Alcohol/Drug/Mental Health Boards; and Medical Examiners' Office.

EXHIBIT 1
Number of Actiq and Fentora prescriptions for Summit and Cuyahoga counties, 1999 – 2018



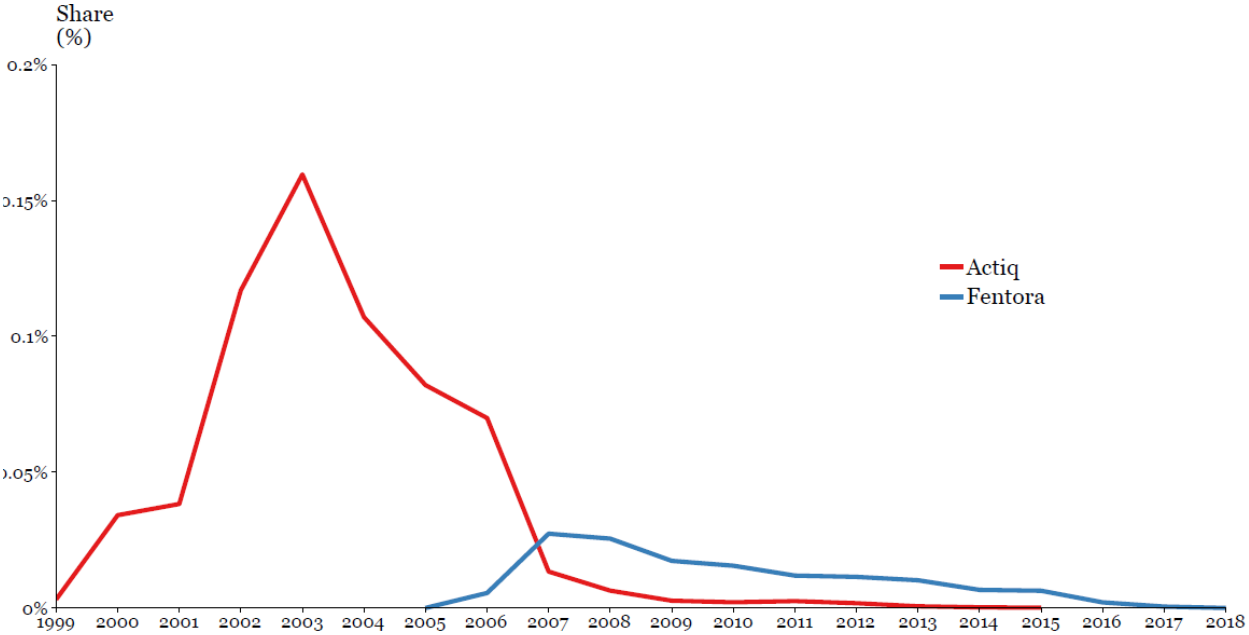
Source: IMS Xponent (ALLERGAN_MDL_02485011; ALLERGAN_MDL_03281086; ALLERGAN_MDL_0330303; ALLERGAN_MDL_03320305); HUD-USPS ZIP Crosswalk, Q3 2018

Note: Includes all records for opioids in IMS Xponent Data for which the product group description contains Actiq or Fentora. Prescriptions are apportioned to counties based on the percent of businesses in a zip code that fall within each county; if the total percent of businesses for a zip code is zero, the percent of all addresses is used. Actiq prescriptions peaked in 2003 with 2,539, and Fentora prescriptions peaked in 2008 with 534.

43. Exhibit 2 shows that Actiq prescriptions reimbursed in 2003 represent approximately 0.16 percent of all prescriptions for opioids sold in the Bellwether Counties in that year. Similarly, the fewer than 600 Fentora prescriptions sold in 2008 correspond to approximately 0.03 percent of all prescriptions sold in the Bellwether Counties in that year. In fact, in the IMS Xponent data, Actiq and Fentora made up only 0.02 percent of all opioid prescriptions from 2006 to 2016.[70]

[70] Workpaper 1.

EXHIBIT 2
Actiq and Fentora share of opioid prescriptions for Summit and Cuyahoga counties, 1999 – 2018



Source: IMS Xponent (ALLERGAN_MDL_02485011; ALLERGAN_MDL_03281086; ALLERGAN_MDL_0330303; ALLERGAN_MDL_03320305); HUD-USPS ZIP Crosswalk, Q3 2018

Note: Shares are calculated using all records for opioids in IMS Xponent Data. Drugs are labeled as Actiq or Fentora if the product group description contains Actiq or Fentora. Prescriptions are apportioned to counties based on the percent of businesses in a zip code that fall within each county; if the total percent of businesses for a zip code is zero, the percent of all addresses is used. Actiq's market share peaked in 2003 with 0.16 percent, and Fentora's market share peaked in 2008 with 0.03 percent.

6.2. Consistent with industry practice, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal and limited to the pricing and commercial availability of those medicines

44. As Dr. Chintagunta's analysis shows, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal. In particular, he analyzes Dr. Rosenthal's IQVIA data and finds that Teva USA and Actavis Generic Defendants did not incur any promotional spending for 8 of their 14 generic opioid drugs. Additionally, Dr. Chintagunta finds that between January 1995 and May 2018, Teva USA and Actavis Generic Defendants' marketing spending on their Schedule II generic opioid drugs made up less than 0.09 percent of the combined marketing spending by all manufacturers of Schedule II branded and generic opioids.[71]

45. Furthermore, Christine Baeder, Teva USA's Chief Operations Officer for U.S. Generics, noted in her deposition testimony that for Teva USA's "promotion" for its generics drugs is limited to providing information on pricing and "product availability."[72] She also stated that

[71] Chintagunta Report, Section V.C.

[72] Deposition of Christine Baeder, January 24, 2019 ("Baeder Deposition"), p. 417:2–5.

transactions are flagged. Dr. McCann's estimates for the same threshold also differ between Section IV and Section V. For example, for the three-times average 12-month threshold, Exhibit 34 reports 40.5% of transactions are flagged in Section IV, whereas only 7.8% of transactions are flagged in Section V.

EXHIBIT 34
Dr. McCann's own methodologies produce inconsistent estimates of flagged transaction In Summit County, 2006–2014

Method	Section IV	Section V
1. Max 6-month	75.4%	74.0%
2. Twice Average 12-month	62.9%	11.1%
3. Three Times Average 12-month	40.5%	7.8%
4. Max 8,000 Dosage Units	52.4%	41.4%
5. Max Daily Dosage Units	86.8%	79.0%

Source: McCann Supplemental Report.

9.4. Dr. McCann's analysis does not accurately reflect the information available to Marketing Defendants

230. Dr. McCann's analysis does not reflect the information that was available to Marketing Defendants. His analysis relies on detailed, transaction-level, ARCOS data. However, "[n]o one within the supply chain ha[d] access to ARCOS."[309] Instead, Dr. McCann claims that Marketing Defendants could have used two different data sources, chargeback data and IQVIA/IMS data, to identify suspicious transactions.[310] Notably, Dr. McCann does not perform any analysis using these datasets, and does not evaluate whether the data were available to Marketing Defendants at the time orders were placed, but only asserts that these datasets are sufficient to monitor transactions for suspicious orders.

231. In particular, Dr. McCann states:

- "Assuming the limited chargeback data provided to me is typical in nature and scope of that available to Manufacturers, the Manufacturer Defendants could have monitored orders from Dispensers, primarily retail and chain pharmacies, if they

[309] See "Questions for the Record from Senator Charles E. Grassley To President and CEO of Healthcare Distribution Alliance, U.S. Senate Committee on the Judiciary – Oversight on the Ensuring Patient Access and Drug Enforcement Act," answered on January 3, 2018. It is also my understanding that ARCOS data only recently became available to Teva in February 2019 (Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva).

[310] McCann Supplemental Report, ¶¶ 18-20.

received chargeback data for all sales of all opioids they shipped to other Manufacturers and to Distributors [emphasis added]."[311]

- "Assuming the IQVIA/IMS Data provided to me is typical in nature and scope to that which was available to Manufacturers, a Manufacturer Defendant could have known where some or all of its drugs were being prescribed [emphasis added]."[312]

232. Contrary to Dr. McCann's claim, neither chargeback data that is available to Marketing Defendants nor IQVIA/IMS data would be sufficient to perform the analysis presented in his Supplemental Report, which is based on ARCOS data.

233. The supply chain of pharmaceutical products in the United States involves three tiers from upstream to downstream suppliers: pharmaceutical manufacturers, wholesale distributors, and dispensers (e.g., pharmacies and hospitals).

234. Pharmaceutical manufacturers produce and manage drug distribution from the manufacturing facilities to wholesale distributors. Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to pharmacies across the country. As an intermediary, wholesale distributors provide warehouse services and inventory management and save costs by efficiently consolidating orders from a variety of pharmacies. Wholesale distributors are the largest purchasers from manufacturers and manage over 91% of pharmaceutical sales revenue.[313] Furthermore, the U.S. pharmaceutical distribution industry is highly concentrated with three companies: AmerisourceBergen, Cardinal Health, and McKesson, collectively comprising over 85% of all revenues from the drug distribution.[314]

235. Pharmacies are at the next downstream level of the supply chain. Pharmacies purchase drugs from wholesale distributors and dispense prescription drugs to patients. There are several types of pharmacies, including chain pharmacies and mass merchants with pharmacies, independent pharmacies, and mail-order pharmacies.[315] In some circumstances, large chain pharmacies can choose to purchase generic drugs directly from

[311] McCann Supplemental Report, ¶ 19.

[312] McCann Supplemental Report, ¶ 20.

[313] "Financing and Distribution of Pharmaceuticals in the United States," JAMA, 2017, 318(1): pp. 21-22. "Modern Distribution Management (MDM). 2016 MDM market leaders: top pharmaceuticals distributors." https://www.mdm.com/2016-top-pharmaceuticals-distributors. 2017. Accessed May, 6, 2019.

[314] "Financing and Distribution of Pharmaceuticals in the United States," JAMA, 2017, 318(1): pp. 21-22. "Modern Distribution Management (MDM). 2016 MDM market leaders: top pharmaceuticals distributors." https://www.mdm.com/2016-top-pharmaceuticals-distributors. 2017. Accessed May, 6, 2019.

[315] From a review of Dr. McCann's production, it appears that he excludes online and mail-order pharmacies from his analysis. This exclusion is not indicated in Dr. McCann's report.

manufacturers.[316] In other circumstances, large pharmacies may negotiate prices directly with manufacturers, but rely on wholesale distributors to deliver the drugs. In this case, the wholesale distributor charges the manufacturer for the difference between the price that the wholesale distributor negotiated with the manufacturer and the price that the pharmacies negotiated with the manufacturer (known as a "chargeback").[317]

236. Dr. McCann opines that Marketing Defendants could have "monitored orders from dispensers, primarily retail and chain pharmacies, if they received chargeback data for *all* sales of all opioids they shipped to other Manufacturers and to Distributors [emphasis added]."[318] However, chargebacks only occur when a Marketing Defendant and a dispenser have contracted a price that is different from the price at which the Marketing Defendant sells to the distributor. It is my understanding that 50% of controlled substances sales for Teva USA do **not** have chargeback data.[319]

237. Furthermore, chargeback contracts generally exist for a manufacturer's larger, established customers. Pharmacies that illegally or inappropriately dispense pharmaceutical products (e.g., pill mills) are unlikely to have contracts with large manufacturers and are highly unlikely to enter chargeback contracts that create documentation of their purchasing and dispensing habits. Put simply, bad actors do not want to generate chargebacks and will buy products at wholesale acquisition costs (WAC) to avoid raising red flags.[320]

238. Dr. McCann also opines that Marketing Defendants could have used IQVIA/IMS data to flag transactions.[321] However, the IQVIA/IMS data available to Marketing Defendants does not connect the prescription data between prescribers and individual pharmacies. As a result Marketing Defendants cannot use IQVIA/IMS data to determine which pharmacies prescribers are using to have prescriptions filled. I understand that Teva USA has requested this information from IQVIA, but has been told IQVIA is not permitted to provide that level of detail to manufacturers. It is also my understanding that some chain pharmacies do not provide data to IQVIA, or provide the data with some information blinded or eliminated.[322]

---

[316] "Large retail chains also buy directly from generic manufacturers, pitting one generic manufacturer against others to obtain the lowest generic price." See Berndt, E. and J. Newhouse, "*Pricing and Reimbursement in US Pharmaceutical Markets*," in P. Danzon and S. Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, New York: Oxford University Press, 2012, p. 218.

[317] "The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then "charges back" the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC)." See "*Follow the Pill*, p. 19.

[318] McCann Supplemental Report, ¶ 19.

[319] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.

[320] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.

[321] McCann Supplemental Report, ¶ 20.

[322] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.